

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

M. Satyanarayana REDDY et al.

Art Unit: 1625

Application No.: 10/801,069

Examiner: C. S. Aulakh

Filed: March 15, 2004

For: NOVEL POLYMORPHIC FORM OF 17- $\beta$ -(N-TER. BUTYL CARBAMOYL)-4-AZA-5- $\alpha$ -ANDROST-1-EN-ONE AND A PROCESS FOR PREPARING IT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

**AMENDMENT**

In response to the Office Action that was mailed on February 15, 2006 for the above-identified application, entry of the following amendments and consideration of the appended remarks are respectfully requested.

A response to the Office Action is due by May 15, 2006, and this response is being filed within the set term.

Upon entry of the amendments, the claims pending for further examination will be those of the listing beginning on page 4. By this amendment, an additional four independent claims are being added, and authorization is being given to charge the \$800.00 fee that is due for presenting these new claims to a deposit account.

IN THE SPECIFICATION:

On page 1, please amend the title to read as follows:

~~NOVEL~~ POLYMORPHIC FORM OF 17- $\beta$ -(N-TER. BUTYL CARBAMOYL)-4-AZA-5- $\alpha$ -  
ANDROST-1-EN-ONE ~~AND A PROCESS FOR PREPARING IT~~

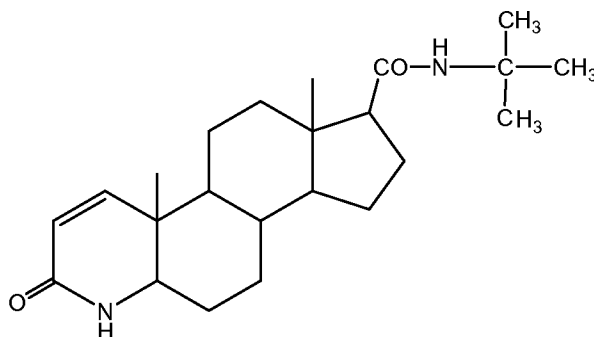
Please add the following as a new page 12 of the application:

ABSTRACT

The present invention relates to a novel polymorphic form of 17- $\beta$ -(N-ter.butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one (Finasteride) of the Formula (I) and processes for preparing the form.

CLAIMS OF THE APPLICATION:

1. (Currently amended) A ~~novel~~ polymorphic Form-III of 17- $\beta$ -(N-ter. butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one having the formula (~~4~~),



which is characterized by the following data:

DSC: exhibits a melting endotherm with a peak temperature of about 262°C and preceded by another minor endotherm at about 245°C and an exotherm at about 253°C. (~~Fig-1~~)

XRD (2 $\theta$ ): 5.32, 10.70, 13.64, 14.96, 15.86, 16.12, 16.56, 17.20, 18.22, 19.60, and 23.04. (~~Fig-2~~)

FT-IR (In KBr): 3427, 3233, 2931, 1679, 1600, 1501, 1451 and 820 cm<sup>-1</sup>. (~~Fig-3~~)

2. (Currently amended) A process for preparing Form-III of 17- $\beta$ -(N-ter. butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one, which comprises:

- (i) dissolving crude 17- $\beta$ -(N-ter. butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one in a water immiscible organic ~~solvents~~ solvent,
- (ii) saturating the solution with ~~less polar organic solvent~~ an aliphatic hydrocarbon either straight chain or branched,
- (iii) concentrating the solution and isolating the Form III of 17- $\beta$ -(N-ter. butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one ~~by conventional methods~~.

3. (Currently amended) The process as claimed in ~~step (i)~~ of claim 2, wherein the water immiscible organic solvent is selected from a halogenated solvent, an aromatic hydrocarbon solvent, or ~~organic solvents selected from an~~ alkyl ~~acetates~~ acetate.
4. (Currently amended) The process as claimed in claim ~~2~~ 3, wherein the halogenated solvent is selected from dichloromethane or chloroform.
5. (Original) The process as claimed in claim 3, wherein the aromatic hydrocarbon solvent is toluene.
6. (Currently amended) The process as claimed in claim 3, wherein the alkyl acetate is ~~selected from~~ ethyl acetate.
7. (Canceled)
8. (Currently amended) A process for preparing the Form-III of 17- $\beta$ -(N-ter. butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one, which comprises,
  - (i) dissolving any of the Form-I, Form-II, Form-IV and Form-V of 17- $\beta$ -(N-ter. butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one in a water immiscible organic ~~solvents~~ solvent,
  - (ii) distilling off 60-70% of the solvent,
  - (iii) saturating the remaining solution with ~~less polar organic solvents~~ an aliphatic hydrocarbon either straight chain or branched, and
  - (iv) concentrating the resultant solution and isolating the Form-III of 17- $\beta$ -(N-ter. butyl carbamoyl)-4-aza-5- $\alpha$ -androst-1-en-3-one ~~by conventional methods~~.
9. (Currently amended) The process as claimed in ~~step (i)~~ of claim 8, wherein the water immiscible organic solvent is selected from a halogenated solvent, an

aromatic hydrocarbon solvent, or ~~organic solvents selected from an~~ alkyl ~~acetates~~ acetate.

10. (Original) The process as claimed in claim 9, wherein the halogenated solvent is selected from dichloromethane or chloroform.

11. (Currently amended) The process as claimed in claim 9, wherein the aromatic hydrocarbon solvent is ~~selected from~~ toluene.

12. (Currently amended) The process as claimed in claim 9, wherein the alkyl acetate is ~~selected from~~ ethyl acetate.

13.-15. (Canceled)

16. (New) Polymorphic Form-III of finasteride, having a differential scanning calorimetry curve substantially in accordance with the curve of Fig. 1.

17. (New) Polymorphic Form-III of finasteride, having an X-ray powder diffraction pattern substantially in accordance with the pattern of Fig. 2.

18. (New) Polymorphic Form-III of finasteride, having an infrared spectrum substantially in accordance with the spectrum of Fig. 3.

19. (New) Polymorphic Form-III of finasteride, having a differential scanning calorimetry curve having a melting endotherm with a peak temperature of about 262°C, a minor endotherm at about 245°C, and an exotherm at about 253°C.

### REMARKS

Claims 1-6, 8-12, and 16-19 are pending for further consideration. In the Office Action, the subject matter of original claims 1, 3, 5, 9, and 10 was considered to be allowable, and original claims 2, 4, 6-8, and 11-15 were rejected. Amendments to the original claims have been made to improve readability and compliance with formal requirements for claims, and claims 7 and 13-15 were canceled. New claims 16-19 were added to better define certain aspects of the invention. The title has been amended for enhancing clarity and the abstract from the PCT publication has been restated on a separate sheet.

#### Objections to the Specification and Claims

An objection to the specification was made, due to the abstract not being present on a separate sheet, and this has been overcome by amendment to the specification. Applicants note, however, that PCT publications always relocate the abstract to the cover page, and the objection is not normally made in a national application that is derived from an international application.

The objection to claim 15 has been rendered moot by cancellation of the claim.

#### Rejections Under 35 U.S.C. § 112

Claims 2 and 8 were rejected as being indefinite for not reciting specific solvents for “water immiscible organic solvents” and “less polar solvents.” By the present amendment, applicants have incorporated the “aliphatic hydrocarbon” limitation from claim 7 into claim 2, in place of “less polar solvents.” Applicants submit that the term “water immiscible organic solvents” is not indefinite, since those skilled in the art will be able to determine whether a solvent from this class will dissolve finasteride, without undue experimentation; this is particularly true since applicants have provided some examples of suitable solvents in their specification. The rejection should be withdrawn.

As suggested in the Office Action, the term “selected from” has been deleted from claims 6, 11, and 12, and the rejection of those claims has been overcome.

The rejections of claims 7 and 13-15 are moot, due to the cancellation of the claims.

Regarding claim 4, the dependency has been corrected to overcome the rejection for lack of antecedent basis.

Rejection Under 35 U.S.C. § 101

The rejection of claim 14 is moot, as that claim has been canceled.

CONCLUSION

Applicants believe that all of the pending claims are in condition for allowance, and an early notification of their allowability is respectfully requested. If any minor matters remain to be resolved prior to disposition of the application, please contact the undersigned to arrange for a telephonic or personal interview to expedite resolution.

Should any additional fees be required in connection with this submission, please charge the necessary amount to Deposit Account No. 50-3221 in the name of Dr. Reddy's Laboratories, Inc.

Respectfully submitted,

/R. A. Franks/

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May 9, 2006

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